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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1631	14

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/295,463	Applicant(s) Cowsert et al.
	Examiner Ardin Marschel	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 18, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *55-103* is/are pending in the applica

4a) Of the above, claim(s) *88-98 and 103* is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *55-87 and 99-102* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *55-103* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☒ Other: *Attachment to PTO_948*

Applicants' arguments, filed 5/18/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Newly submitted claims 88-98 and 103 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The validation of a gene function to which claims 88-98 and 103 are directed is distinct from the modulation of expression of a target nucleic acid in that said validation is directed to gene function of an expression product whereas in contrast the modulation of target nucleic acid expression is directed to whether or not or to controlling the extent of target expression which are two completely different aspects of nucleic acid practice and thus completely different searches thus documenting the undue search burden if searched together, both being extensive subject areas in biotechnology.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 88-98 and 103 are withdrawn from consideration as being directed to a non-elected invention.

See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 was mailed with Paper No. 8, mailed on 9/28/00. Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claims 55-87 and 99-102 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In all of the above listed claims the preambles direct the claim practice to modulation of expression or antisense practice whereas confusingly none of the assay steps are limited to either of these practices. Thus, the claims are vague and indefinite as to whether the preamble controls the metes and bounds of the claims or the broader actual steps in the claimed methods. An additional unclarity as to the metes and bounds of the claims is that many claims also do not define or generate the virtual compounds via modulation of nucleic acid expression or antisense

activity. Thus, again the metes and bounds of the claims are vague and indefinite regarding such virtual compound selection. See, for example, claim 56 wherein the virtual compounds are selected by some undefined "defined criteria". The presence of "defined" in the phrase "defined criteria" lacks any specificity as to what is meant and thus lacks any definition of its metes and bounds. Clarification via clearer claim wording is requested.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order

for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 55-87 and 99-102 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Agrafiotis et al.(P/N 5,463,564); taken in view of Uhlmann et al.(1990); taken further in view of Dower et al.(P/N 5,639,603); taken further in view of either of Haff et al.(P/N 5,720,923) or Harris et al.(P/N 5,650,122).

The instant claims are directed to target nucleic acid expression modulation or, specifically, antisense gene modulation wherein virtual compounds are designed and then synthesized and tested via computer controlled real time PCR or ELISA testing.

Agrafiotis et al. generically describes computer controlled design of a variety of compounds, including drugs, etc., computer controlled synthesis and computer controlled testing thereof taken as a whole thus motivating automated specifics of design, synthesis, and testing of generic compounds as desired.

Uhlmann et al.(1990) describes numerous generalities in a review directed to antisense gene or target nucleic acid modulation as including synthesis and testing of such antisense reagents thus motivating the preparation, synthesis, and testing of such compounds. These compounds hybridize to specific nucleic acid targets for antisense usage.

Dower et al. describes automated oligonucleotide synthesis of hybridizable oligonucleotides.

Automated PCR or ELISA testing of compounds is described in Haff et al. and Harris et al., respectively.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to perform desired compound design including drugs such as antisense drugs via Agrafiotis et al. combined with Uhlmann et al. and synthesize such oligonucleotides via Dower et al. as required for antisense practice and then perform assays as desired utilizing the Haff et al. and/or Harris et al. disclosures thus resulting in the practice of the instant invention.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

August 10, 2001

ARDIN H. MARSCHEL
PRIMARY EXAMINER